#### CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

## ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

#### 

Claims 5-12 have been amended and claims 13-25 have been cancelled. Claims 5-12 and 26 are now pending. It is believed that no new matter has been added. The applicants reserve the right to pursue the subject matter of claims 13-25 in a divisional application.

#### Information Disclosure Statement

While an additional copy of the references cited in the IDS are being provided, the examiner is directed toward the applicants transmittal letter for filing under 35 U.S.C. 371 which indicates that a copy of the references were submitted and the PTO acknowledged that such references were received (see Form PCT/DO/EO/903 - signed by Vonda Wallace). As such, the date of the originally filed IDS is still valid and the applicants' request consideration of the references in the next office action.

For situations where it appears the references become separated from the file after receipt by the PTO (especially when the references are U.S. or foreign patents), the applicants request that the examiner, in the interest of advancing prosecution, utilize their databases (e.g. EAST/WEST, FPAS or WPIDS) to obtain the references of record or at the very least contact the applicants so that an additional copy can be faxed for their consideration. If the examiner contacted the

applicants about the missing references, there is no Interview Summary Record of such a discussion.

### Specification Objections

The specification was objected to because of the structure listed for the epicatechin was stated by the examiner to be different than the structure listed in the CAS Registry files. However, the structures are the same compounds, i.e. the 3,4-dihydroxyphenyl component of the epicatechin can rotate around the 2R bond, see below:

With regard to Example 2 on page 17, it is unclear what is the basis for the examiner's objection. It is clear that green tea extract is intended to be part of the skin cream of example 2 which is consistent with the applicants' disclosed invention (i.e. adequately described). If the examples are objected to because no specific amount of green tea extract is disclosed in the list of ingredients, the examiner is reminded that no recitation of working examples are necessary (i.e. adequately enabled), especially in the present application where other working examples are present (see MPEP 2164.02).

#### 35 U.S.C. 112, first paragraph rejection

Claims 5-12 have been amended to remove the term "prophylaxis" and as such this portion of the rejection is believed to have been addressed.

Claim 26 was rejected by the examiner as not being adequately described for "strengthening the lipid barrier or increasing the synthesis rate of ceramides of human skin". However, no reasons or explanation was given by the examiner as to why it is believed that the applicants have not adequately described their invention.

The examiner is reminded that MPEP 2163, section I. A. states:

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). - emphasis added by applicants.

#### 35 U.S.C. 112, second paragraph rejection

Claims 5-12 were rejected as being indefinite for using the phrase dry skin "conditions". While the applicants assert that the phrase has clear meaning to one of ordinary skill in the cosmetics art, the term "conditions" has been deleted. The applicants reserve the right to pursue the claims prior to amendment in a divisional applications if necessary.

Claims 5-12 were rejected as being indefinite for using the term "a therapeutically effect (sic) amount". This is a commonly used phrase which can be found in any number of previously

issued patents with method of use claims (see Class 424 and Class 514 especially) and is intended to refer to the effective amount for the disease/condition which is being treated as stated in the preamble of the claim. The applicants submit that the claim language is definite as written, but if this is the only issue preventing a Notice of Allowance, the examiner is authorized to incorporate redundancy by drafting an Examiner's Amendment which substitutes the phrase "a therapeutically effective amount" for the phrase "a therapeutically effective amount for the treatment and/or care of dry skin".

See above explanation ("Specification Objections") about the figure on the bottom of page 4 in the specification which supports the assertion by the applicants that Claim 8 is definite as written.

#### 35 U.S.C. 102(b) rejection

Claims 5-12 and 26 remain rejected (after the applicants' amendment) by the examiner as being anticipated by the abstract for BR 9303217 A (Kurose et al.)

Kurose et al. does not anticipate the applicants' claims 5-12 as amended. MPEP 2131 states that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.....The identical invention must be shown in as complete detail as is contained in the ...claim." (emphasis added by applicants). As such, Kurose et al. does not teach the weight limitations of the catechin components or direct the skilled artisan to a specific method of use, i.e. Kurose et al. only hypothesizes ("may have") about a laundry list of potential utilities (ten in all).

Kurose et al. does not disclose the invention represented by the applicants claim 26 (i.e. a method of strengthening the lipid barrier and/or increasing the synthesis rate of ceramide of human skin)

and as such does not anticipate this claim.

Claims 5-12 and 26 remain rejected (after the applicants' amendment) by the examiner as being anticipated by Znaiden et al. (U.S. Patent 5,523,090).

It was presumed that claims 5-12 were included in the rejection because of the use of the term "conditions"??? In any event, the claims as amended clearly define the method of use to be for the dry skin which is not equivalent to the treatment of cellulite. Likewise, Znaiden et al. does not teach the inventive concept represented by the applicants' claim 26.

Claim 26 remains rejected (after the applicants' amendment) by the examiner as being anticipated by Ahluwhalia (WO 96/26705).

Ahluwhalia method of use is directed toward reduction of mammalian hair growth which does not anticipate a method of strengthening the lipid barrier and/or increasing the synthesis rate of ceramide of human skin as stated in the applicants' claim 26.

#### 35 U.S.C. 103(a) rejection

Claims 5-12 and 26 remain rejected (after the applicants' amendment) by the examiner as being obvious over Kurose et al. (abstract) in combination with Znaiden et al. (each reference cited above).

As stated above, Kurose et al. does not teach the applicants invention as Kurose et al. does not describe the applicants weight limitations for catechins and does not teach the specific method of use claimed by the applicants.

Znaiden et al. does not remedy the deficiencies of the Kurose et al. references as it does not recognize using the catechins for the method described by the applicants and are directed toward compositions which have different compenents and different intended use. Furthermore, there is no explanation as to the motivation for combining the teachings of Znaiden et al. into the teachings of Kurose et al., i.e. statement of "reasonable expectation of success" by the examiner only establishes that the references *could be* combined (see MPEP 2143.02). However, this does not supply the motivation or suggestion to modify the reference cited as described in MPEP 2143.01; i.e. the combination represents hindsight or an obvious-to-try rationale.

#### Closing

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

Applicants believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

y Howard C. Lee

Howard C. Lee

Reg. No. 48,104

220 East 42<sup>nd</sup> Street 30<sup>th</sup> Floor

New York, New York 10017 (212) 808-0700

## CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents, Washington, D.C. 20231, on the date indicated below:

Date: 8 March 2002

By Howard C. Lee

Howard C. Lee

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#### COPY OF CLAIMS SHOWING AMENDMENTS MADE

- A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] in a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of a composition comprising of 0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof, based on the total weight of the composition.
- 6. The method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin or gallic ester of a catechin are selected from the group consisting of (-)-catechin, (+)-catechin, (-)-catechin gallate, (-)-gallocatechin gallate, (+)-epicatechin, (-)-epicatechin, (-)-epicatechin gallate.
- 7. The method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin is

or a gallic ester thereof. --

8. The method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin is

or a gallic ester thereof.

- 9. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 5, wherein the catechin or gallic ester of a catechin is obtained from a plant.
- 10. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 9, wherein the catechin or gallic ester of a catechin is obtained from a plant from the *Theaceae* plant family.
- 11. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] according to Claim 9, wherein the catechin or gallic ester of a catechin is obtained from the plant species Camellia sinensis.
- 12. A method for the [prophylaxis,] treatment, and/or care of dry skin [conditions] in a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of an extract from a plant or plant parts which comprises a catechin, a gallic ester of a catechin, or mixtures thereof.

26. A method for strengthening the lipid barrier and/or increasing the synthesis rate of ceramide of human skin in a human in need thereof that comprises applying to the skin of a patient in need thereof a therapeutically effect amount of the composition according to Claim 13.

United States Patent and Trademark Office UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademerk Office COMMISSIONER OF PATENTS AND TRADEMARES Weshington, D.C. 2023 APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/701,710 12/01/2000 Volker Schreiner Beiersdorf 688-VMM 7950 03/29/2002 Norris McLaughlin & Marcus P.A. EXAMINER 30th floor 220 East 42nd street New York, NY 10017 PAPER NUMBER

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)



#### UNITED STATES PATENT AND TRADEMARK OFFICE

INDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE WASHINGTON, DC 2023 WWK.USDO.CO

Paper No.

# Notice of Non-Compliant Amendment (37 CFR 1.121)

CFR 1	The amendment filed on 3.18-62 is considered non-compliant because it has failed to meet the requirements of 37 in 121, as amended on September 8, 2000 (see 65 Fed. Reg. 54603, Sept. 8, 2000, and 1238 O.G. 77, Sept. 19, 2000). In order for mendment to be compliant, applicant must supply the following omissions or corrections in response to this notice.
THE	FOLLOWING ITEMS ARE REQUIRED FOR COMPLIANCE WITH RULE 1.121 (APPLICANT NEED NOT RE-SUBMIT ENTIRE AMENDMENT):
	1. A clean version of the replacement paragraph(s)/section(s) is required. See 37 CFR 1.121(b)(1)(ii).
□ .	2. A marked-up version of the replacement paragraph(s)/section(s) is required. See 37 CFR 1.121(b)(1)(iii).
	3. A clean version of the amended claim(s) is required. See 37 CFR 1.121(c)(1)(i).
	4. A marked-up version of the amended claim(s) is required. See 37 CFR 1.121(c)(1)(ii).
Explai	nation: page 12 to missing from andt
Eog fu	tesse provide specific details for correction to assist the applicant. For example, "the clean version of claim 6 is missing.")  arther explanation of the amendment format required by 3.7 CFR 1.121, see MPEP § 714 and the USPTO website at /www.uspto.gov/web/offices/dcom/olia/pbg/sampleaf.pdf. A condensed version of a sample amendment format is attached.
<u>.</u>	PRELIMINARY AMENDMENT: Unless applicant supplies the omission or correction to the preliminary amendment in compliance with revised 37 CFR 1.121 noted above within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.
	AMENDMENT AFTER NON-FINAL ACTION: Since the above-mentioned reply appears to be bona fide, applicant is given a TIME PERIOD of ONE MONTH or THIRTY DAYS from the mailing of this notice, whichever is longer, within which to supply the omission or correction notest above in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).
2 Lemi	Instruments Examiner (LIE)

(Rev. 12/01)

# **FACSIMILE COVER SHEET**

NORRIS MCLAUGHLIN & MARCUS, P.A. 220 East 42<sup>nd</sup> Street 30<sup>th</sup> Floor New York, New York 10017

Tel.: (212) 808-0700 Fax.: (212) 808-0844

Date: July 09, 2002

To: Examiner Alysia Berman

US Patent and Trademark Office

Tel. 703-308-4638 Fax: 703-872-9306

Subject: USSN 09/701,710

Our Ref.: Beiersdorf 688-HCL

From: Howard C. Lee 9 July 2002 Howard C. Lee

Comments: Pursuant to our telephone conversation today regarding reply to the Office Action dated 12/20/01, and response to Notice of Non-Compliant Amendment dated 3/29/02, attached

is a copy of each of the following:

return receipt postcard dated April 18, 2002 stamped April 23, 2002;

- return receipt postcard dated April 18, 2002;

- letter to the Examiner, Alysia Berman, in response to Notice of Non-Compliant Amendment dated 3/29/02;
- original response to office action dated 12/20/01, including: stamped return receipt postcard, Transmittal Letter, Amendment, and copy of claims showing amendments made;
- Office communication including Notice of Non-Compliant Amendment

If you have any questions or need further information, please contact us.

You should receive 21 pages including this cover sheet.

The information contained in this facsimile message is intended only for the personal and confidential use of the recipient(s) named above. This message may be an attorney-client communication and as such is privileged and confidential. If the reader of this message is not the intended recipient or an agent responsible for delivering it to the intended recipient, you are hereby notified that you have received this document in error and that any review, dissemination, distribution, or copying of this message is strictly prohibited. If you have received this communication in error, please notify us immediately at the number above and discard the original message.

CASE # Beiersdorf 688/100718-275

Serial No. 09/701,710

DATE MAILED: April 18, 2002

.DATE DUE:

The stamp of the Patent Office hereon may be taken as acknowledgement of receipt, on the date stamped, of the following:

1. Letter to Examiner, Alysia Berman, in response to Notice of Non-Compliant Amendment dated March 29, 2002

2. Copy of original Response to Office Action dated December 20, 2001, including:

- copy of stamped return receipt postc

- copy of Transmittal Letter - copy of Amendment (pp. 1-10)

- copy of Copy of Claims Showing Amendments made (pp. 11-13)

3. copy of Wifice communication including Notice of Non-Compliant Americant

The stamp of the Patent Office hereon may be taken as acknowledgement of receipt, on the date stamped, of the following:

- Letter to Examiner, Alysia Berman, in response to Notice of Non-Compliant Amendment dated March 29, 2002
- 2. Copy of original Response to Office Action dated December 20, 2001, including:
  - copy of stamped return receipt postcard
  - copy of Transmittal Letter
  - copy of Amendment (pp. 1-10)
  - copy of Copy of Claims Showing Amendments Made (pp. 11-13)
- 3. copy of Office communication including Notice of Non-Compliant Amendment

Beiersdorf 688/100718-275 6713-Dr. Wi-ka

#### IN THE UNITED STATES PATENT AND TRADEMARKS OFFICE

APPLICANTS:

V. Schreiner et al.

SERIAL NO.:

09/701,710

**FILED** 

December 1, 2000

**FOR** 

COSMETIC OR DERMATOLOGIC PREPARATIONS

CONTAINING CATECHINS OR GREEN TEA EXTRACT

ART UNIT

1619

**EXAMINER:**:

Alysia Berman

April 18, 2002

Hon. Assistant Commissioner for Patents Washington, D.C. 20231

Ms. Berman:

Enclosed is a copy of our Response to the Office Action dated 20 December 2001, which was originally filed with your office on March 8, 2002 and copy of the Notice of Non-Compliant Amendment. Also, please be advised that our original submission contained page 12.

Please make the above-mentioned correction at your earliest convenience.

Respectfully Submitted,
NORRIS McLAUGHLIN & MARCUS

Rv∙

Howard C. Lee

Reg. No. 48,104

HCL/vif Enclosures

220 East 42<sup>nd</sup> Street 30<sup>th</sup> Floor New York, New York 10017 Tel. (212) 808-0700 Fax (212) 808-0844 CASE # 100718/275/Beiersdorf 688-HCL SERIAL NO.: 09/701,710 DATE MAILED: March 8, 2002 DATE DUE: March 20, 2002

The stamp of the Patent Office hereon may be taken as acknowledgment of receipt, on the date stamped, of the following:

- 1. Transmittal Form
- 2. Amendment Under 37 CFR §1/111
  - a. Copy of Claims Showing Amendments Made
  - b. Copy of Postcard dated December 1, 2000 showing receipt of IDS
  - c. Copy of the PTO 1449/previously submitted
  - d. Copy of three references (previously submitted)

